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# **REMARKS**

Claims 62-102 are pending in the present application. Claims 62-81 and 92-102 are canceled herein without prejudice. Claim 103 is added. Support for claim 103 is found throughout the specification as originally filed, and no new matter is added. Reconsideration of this application is respectfully requested in view of the following discussion.

## Duty of Disclosure

Upon information and belief, Applicant has properly named all inventors in the present application. However, information has been brought to the attention of Applicant that possible addition of another inventor may be warranted. Applicant is analyzing the information and will promptly advise the Examiner to the extent any change to the inventive entity is appropriate.

# 1. Drawings

The drawings are objected to under 37 CFR 1.83(a). The Office indicated that "the device body comprising three, four or five deviations or the body member being z-shaped must be shown or the feature(s) canceled from the claim(s)."

Applicants submit herewith new proposed drawings as requested by the office, wherein an example of a z-shaped device is shown in Fig. 8, and wherein examples of a body comprising five, four, and three deviations is shown in Figs. 9A-C respectively. Reconsideration and withdrawal of the objection is respectfully requested.

### 2. 35 U.S.C. §112 Rejections

Claims 82-91 are rejected under 35 U.S.C. §112, first paragraph. The Office asserts that it is not clear what the claimed "body member having at least two, three, four or five deviations from a linear path" means "since there is no drawing or further explanation of what deviations mean."

Applicants respectfully submit that it would be clear to one of skill in the art what is meant by deviations from a linear path. To deviate is generally understood as meaning to turn aside or diverge from a course or way. Thus, a deviation from a linear path would mean that it turns aside or diverges from the linear path..

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Accordingly, Applicants respectfully submit that claims 82-91 are in accordance with 35 U.S.C. §112, first paragraph. Reconsideration and withdrawal of the rejection is respectfully requested.

# 2. 35 U.S.C. §102 Rejections

#### Makower et al.

Claims 82-91 are rejected under 35 U.S.C. §102(e) over US Pub No. 2005/0240147 to Makower et al.

Applicants respectfully traverse because Makower et al does not properly qualify as prior art.

The subject application claims priority from provisional application 06/228,934, filed on August 30, 2000 and from U.S.S.N. 09/888,092 (U.S. Patent 6,719,750), filed on June 22, 2001. Thus, Applicants' date of invention is at least as early as June 22, 2001.

The Makower et al. application has a filing date of April 21, 2004 and publication date of October 27, 2005. Thus, the earliest possible priority date of Makower is April 21, 2004. Under 35 U.S.C. §102(e)(1), Makower must have been published (October 27, 2005) before Applicants' date of invention (Applicants' date of invention is at least as early as June 22, 2001), which is not the case. 35 U.S.C. §102(e)(2) does not apply since the Makower application has not been granted. Nonetheless, even if Makower is granted, the filing date of Makower (April 21, 2004) is still after Applicants' date of invention (at least as early as June 22, 2001).

Reconsideration and withdrawal of the rejection is respectfully requested.

### Apolet et al.

Claims 82-91 are rejected under 35 U.S.C. §102(b) over US Patent No. 5,364,343 to Apolet et al.

Applicants respectfully traverse.

Applicants recite in claim 82 a method for treating a patient comprising: (a) providing a delivery device comprising a non-linear shaped body member having at least two deviations

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from a linear path and (b) inserting into a patient ear the device whereby the body member resides in the patient ear and a therapeutic substance is administered to the patient via the body member.

Applicants recite in claim 103 a method for treating a patient comprising: (a) providing a delivery device comprising a therapeutic substance and a non-linear shaped body member having at least two deviations from a linear path and (b) inserting into a patient ear the device whereby the body member resides in the patient ear and the therapeutic substance is administered to the patient via the body member.

Apolet at least fails to teach or suggest a method wherein a delivery device comprising a non-linear shaped body member having at least two deviations from a linear path is inserted into a patient ear. Rather, Apolet describes an irrigation device 11 having a main body 21 generally conical shape (Fig. 2), or a main body 31 which may have protrusions along its length (Fig. 3).

Thus, claims 82 and 103 are patentable over Apolet. Claims 83-91 depend from claim 82 and, likewise, are patentable over Apolet. Reconsideration and withdrawal of the rejection is respectfully requested.

#### Grossan or Williams

Claims 82-91 are rejected under 35 U.S.C. §102(b) over US Patent No. 4,206,756 to Grossan or US Patent No.4,904,238 to Williams.

Applicants respectfully traverse.

Grossan at least fails to teach or suggest a method wherein a body member, which resides in the patient ear, has at least two deviations from a linear path. Rather, Grossan describes a tubular connector 72 ending is a convex smooth portion 11, which is situated within the ear (see col. 3, lines 50-52). The convex smooth portion 11 does not have at least two deviations from a linear path.

Williams is also deficient in that it at least fails to teach or suggest a method wherein a body member, which resides in the patient ear, has at least two deviations from a linear path.

Rather, Williams describes a surgical tip 38 for insertion into a surgical incision (see, e.g., col. 5,

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lines 2-5). The surgical tip 38 may be gradually slanted or rounded and has no interruptions, junctions, joints or protrusions (see, e.g., col. 6, lines 24-30). Nowhere does Williams describe or suggest one or more deviations from a linear path.

Accordingly, claims 82 and 103 are patentable over Grossan and Williams. Claims 83-91 depend from claim 82 and, likewise, are patentable over Grossan and Williams. Reconsideration and withdrawal of the rejection is respectfully requested.

## **Huttner or Dimick**

Claims 82-91 are rejected under 35 U.S.C. §102(e) over US Patent No. 6,706,023 to Huttner et al or US Patent No. 6,764,470 to Dimick.

Applicants respectfully traverse.

Huttner at least fails to teach or suggest a method wherein a body member, which resides in the patient ear, has at least two deviations from a linear path. Rather, Huttner describes an irrigation device 10 having a generally conical shape with a distal tip 32 and a flared member 30 terminating at a base 34. The base 34 is larger than the circumference of the orifice being examined to prevent the irrigation device from being over inserted into the orifice being examined. (See col. 3, lines 42-55) Thus, base 34 does not enter the ear. Generally, the irrigation device 10 is stopped from over insertion by the sides of the orifice being examined at a point between the base 34 and the tip 32 of the flared member 30. (See col. 3, lines 55-57) Thus, the portion of Huttner's device that resides in the patient's orifice is, at the most, between the tip 32 and base 34. This portion does not have at least two deviations from a linear path.

Further, Dimick does not remedy the deficiencies of Huttner because Dimick does not properly qualify as prior art under any section of 35 U.S.C. §102.

Dimick has a filing date of December 3, 2002 and claims priority from provisional application 60/336,646, filed on December 3, 2001. Dimick issued on July 20, 2004.

As set forth above, Applicants claim priority from provisional application 60/228,934, filed on August 30, 2000 and from U.S.S.N. 09/888,092, which issued as U.S. Patent 6,719,750 and was filed on June 22, 2001.

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Thus, Applicants effective filing date, which is at least as early as June 22, 2001, is prior to Dimick's earliest effective filing date (December 3, 2002) and is earlier than Dimick's issue date (July 20, 2004).

Accordingly, claims 82 and 103 are patentable over Huttner. Dimick does not properly quality as prior art. Claims 83-91 depend from claim 82 and, likewise, are patentable over Huttner. Reconsideration and withdrawal of the rejection is respectfully requested.

# **CONCLUSION**

It is respectfully submitted that the subject application is in a condition for allowance. Early and favorable action is requested. If for any reason a fee is required, a fee paid is inadequate or credit is owed for any excess fee paid, you are hereby authorized and requested to charge Deposit Account No. **04-1105**.

Dated: april 17,2006

Respectfully submitted,

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